VII

510K SUMMARY

Device Name: ROSTAM Blunt end and Round (Petal-Tip) Tampons

Legally marketed device: These Tampons are substantially equivalent to legally marketed Rostam tampons with applicators.

Device description: Rostam Blunt end and Round end Tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be provided with 5 absorbencies, junior (MINI), regular, slender regular, super and super plus.

These Tampons are made from rayon and cotton and cotton cord.

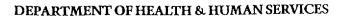
The material used in these tampons are similar to those used in other legally marketed tampons.

Intended Use: These tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing and safety evaluations of tampon components was historically carried out. The results of these tests demonstrate that these Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of these Tampons. In addition to the review of existing toxicological data in the public literature, the following tests were conducted and are relevant to the safety of Rostam blunt end and round end tampons.

- irritation testing
- **♦** sensitization testing
- ♦ acute oral toxicity
- ♦ eye irritation testing
- cytotoxicity testing





AUG 3 2000

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Rostam Ltd. c/o Robert A. Stabb, Ph.D. RTA, Inc. 73 Franklin Turnpike Allendale, NJ 07401 Re: K001641

Unscented Menstrual Tampon Dated: May 25, 2000 Received: May 30, 2000

Regulatory Class: II

21CFR §884.5470/Procode: 85 HEB

Dear Dr. Stabb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours

Daniel G. Schultz, M.D.

Captain, USPHS

Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation Center for Devices and Radiological Health

Enclosure(s)

		Pageof
510(k) Number (if know	m): applied for	X001641
Device Name: Rostam blunt and round tip applicator tampons		
Indications For Use:		·
As a Class II device (21 CFR 884.5460 and	ce, the menstrual tand 21 CFR 884.5470)	ampon is defined as follows:
Rostam applicator material that is in menstrual or other	nserted into the vac	cellulosic or synthetic gina and used to absorb
	•	
•		
(PLEASE DO NOT WRIT	TE BELOW THIS LINE - CONT	TINUE ON ANOTHER PAGE IF NEEDED)
Concurre	ence of CDRH, Office of D	Crisco Established (ODE)
	Division Sign-Off) Division of Reproductive, Abdo	<i></i>
Procedure	510(k) Number <u>KOO16</u>	41
Prescription Use (Per 21 CFR 801.109)	OR	Over-The-Counter Use

(Optional Format 1-2-96)